

# UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,704	08/15/2000	CATHARINA SVANBORG	032313-004	3220
21839	7590 01/08/2004		EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			ROBINSON, HOPE A	
POST OFFIC	E BOX 1404 IA, VA 22313-1404		ART UNIT PAPER NUMBER	
, , , , , , , , , , , , , , , , ,			1653	
			DATE MAILED: 01/08/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

		<del></del>				
Office Action Summary		Application No.	Applicant(s)			
		09/554,704	SVANBORG ET AL.			
		Examiner	Art Unit			
		Hope A. Robinson	1653			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status						
1)⊠	Responsive to communication(s) filed on 22 O	october 2003.				
2a)⊠	This action is <b>FINAL</b> . 2b) ☐ This	action is non-final.				
3)□	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
<ul> <li>4) Claim(s) 1-16 and 19-49 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5) Claim(s) 1-13,19-32,34 and 36-46 is/are allowed.</li> <li>6) Claim(s) 14-16,33,35 and 47-49 is/are rejected.</li> <li>7) Claim(s) is/are objected to.</li> <li>8) Claim(s) are subject to restriction and/or election requirement.</li> </ul>						
Application Papers						
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>						
Priority under 35 U.S.C. §§ 119 and 120						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.  37 CFR 1.78.  a) The translation of the foreign language provisional application has been received.  14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.						
Attachmen	t(s)					
2) Notic	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)			

Application/Control Number: 09/554,704

Art Unit: 1653

### **DETAILED ACTION**

1. Applicant's response to the Office Action mailed May 22, 2003 on October 22, 2003 is acknowledged.

## Claim Disposition

- 2. Claims 17-18 have been canceled. Claims 47-49 have been added. Claims 1-16 and 19-49 are pending and under examination.
- 3. The following grounds of rejection are applicable:

### Abstract

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

## Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1653

5. Claims 14-16, 33, 35 and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 15 still lack antecedent basis as the claim recites "a molten globule inducing reagent" and the claims from which it depends recite "a conversion reagent". The dependent claim hereto is also included.

Claim 20 remains indefinite because the claim requires a "mutated form" of the native form of alpha-lactalbumin wherein the calcium binding sites are modified, however, there is no indication as to how they are modified. The dependent claims are also included.

Claim 21 remains indefinite because the claim recites, "cysteine residues of the alphalactalbumin are mutated" and it is unclear as to what the mutation is.

Claim 33 remains indefinite as to the recitation of "low pH", what is considered "low".

Claim 48 lacks antecedent basis as the claim is directed to a "non-human" product obtained from the method of independent claim 1 which is drawn to a human product only (see also claim 49).

6. Applicant's arguments filed on October 22, 2003 have been considered. It is noted that the response on page 10 indicates that an abstract was filed, however an abstract on a separate page was not found, thus the objection remains. The response indicates that claims have been amended therefore, the rejection under 35 U.S.C. 112, first paragraph should be withdrawn. However, note that the rejection remains for the reasons stated above, see for example claim 33

Application/Control Number: 09/554,704

Art Unit: 1653

where the term "low pH" is recited, although claims should as claim 10-11 were amended to remove that terminology. Claim 21 was partially amended as all issues raised were not addressed in the response. Claims 14-16 still lack antecedent basis as the independent claim recites "conversion reagent". Claim 20 remains rejected as the amendment provides an end result or resultant effect but does not address the issue raised of "how mutated" (see also claim 21 regarding "what mutation" is referred to). In addition, new grounds of rejections were instituted over the newly submitted claims 47-49 for the reasons stated above.

#### Conclusion

7. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Application/Control Number: 09/554,704

Art Unit: 1653

8. Claims 1-13, 19-32, 34 and 36-46 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

ROBERT A. WAX